PTC/SB05A(10-01)
Approved for use through 10:01/2002, 0x80 851-0001
US Patent & Tradement Office: U.S. DEPARTMENT of Cobsection
of Information unless if contains a visit Quill control number.

Complete if Known Substitute for form 1449A/PTO
INFORMATION DISCLOSURE Complete if Known 10/815,557 **Application Number** STATEMENT BY APPLICANT March 31, 2004 Filing Date **First Named Inventor** Engelhardt, John 1653 **Group Art Unit Examiner Name** Unknown Attorney Docket No: 875.085US1

	***************************************	US PAT	ENT DOCUMENTS	
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2002/0197237A1	12/26/2002	Engelhardt, J., et al.	01/22/2002
	US-2002/0076754A1	06/20/2002	Sun, Liangwu, et al.	04/20/2001
···································	US-2002/0131956A1	09/19/2002	Walsh, C. E., et al.	03/12/2002
	US-2003/0103939A1	06/05/2003	Engelhardt, J. E., et al.	07/12/2002
	US-5,604,090	02/18/1997	Alexander, Ian E., et al.	06/06/1994
	US-5,691,176	11/25/1997	Lebkowski, J. S., et al.	06/02/1995
	US-5,831,068	11/03/1998	Nair, S. K., et al.	08/20/1996
	US-5,834,182	11/10/1998	Alexander, Ian E., et al.	02/25/1997
	US-5,843,742	12/01/1998	Natsoulis, G., et al.	09/08/1995
	US-6,083,702	07/04/2000	Mitchell, L. G., et al.	08/13/1998
	US-6,156,303	12/05/2000	Russell, D. W., et al.	06/11/1997
	US-6,200,560	03/13/2001	Couto, L. B., et al.	12/22/1999
	US-6,221,349	04/24/2001	Couto, Linda B., et al.	07/30/1999
	US-6,287,569	09/11/2001	Kipps, T. J., et al.	04/06/1998
	US-6,436,392	08/20/2002	Engelhardt, John F., et al.	03/25/1999
	US-6,544,786	04/08/2003	Xiao, Xiao, et al.	10/13/2000

	FOF	REIGN PATENT (	DOCUMENTS	
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T²
	CA-2302627	09/23/2001	Yves, B., et al.	
	EP-1153612A1	11/14/2001	Tsurou, T., et al.	
	WO-94/13788A1	06/23/1994	Coruzzi, Laura A., et al.	
	WO-95/07351A1	03/16/1995	Jarrell, Kevin A.	
	WO-95/15384A1	06/08/1995	Johnson, David C., et al.	
	WO-97/22250A1	06/26/1997	Mitchell, Lloyd G.	
	WO-98/09657A2	03/12/1998	Wilson, James M., et al.	
	WO-98/24479A1	06/11/1998	Snyder, R., et al.	
	WO-98/53839A2	12/03/1998	Stoven, V., et al.	•
	WO-99/60146A1	11/25/1999	Engelhardt, John F., et al.	
	WO-00/47220A1	08/17/2000	Kenten, J. H., et al.	
	WO-00/75365A2	12/14/2000	Engelhardt, J. F., et al.	
	WO-01/25465A1	04/12/0001	Engelhardt, J. F.	
	WO-01/83692A2	11/08/2001	Hildinger, M., et al.	
· · · · · · · · · · · · · · · · · · ·	WO-02/087306A2	11/07/2002	Callamaras, N., et al.	
	WO-2004/090145A2	10/21/2004	Engelhardt, J. F., et al.	

Kevin K. Hill

PTO/SB05A(10.01)
Approved for use through 10/31/2002, CALB 651-0031
Peters & Tradement Office, U.S. DEPARTMENT OF COLLEGERS

	Under the Peperwark Reduction Act of 1995, no persons are	required to respond to a collection of information unless it contains a valid CMS control number	
Substitute for form 1449A/PTO INFORMATION DISCLOSURE	Complete if Known		
STATEMENT BY APPLICANT	<b>Application Number</b>	10/815,557	
(Use as many sheets as nocessary)	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 2 of 16	Attorney Docket No: 8	375.085US1	

		R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		"(S)-(+)-Camptothecin; 4-Ethyl-4-hydroxy-1H-pyrano[3', 4': 6,7] indolizino [1,2-b]	
		quinoline-3, 14 (4H, 12H) dione", Calbiochem, Camptothecin, Camptotheca	
		acuminata,(October 2, 2000),1-2	
		"Adriamycin; 14-Hydroxydaunomycin, HCI", Calbiochem, Doxorubicin,	T
		Hydrochloride, Catalog Number 324380,(October 21, 1998),1-2	
		"Aminoglycoside antibiotic. Inhibits myeloperoxidase-dependent oxidant cell	
		injury", Calbiochem, Tobramycin, Free Base, Catalog Number 614005,(August	
		26, 1999),1	1
		"Cancer Research", Contribution to Society,	
		http://www.bikaken.or.jp/mcrf_e/contributiion,(December 4, 2000),2 pages	
		"Carbobenzoxy-L-leucyl-L-leucinal", Calbiochem, MG-132, Catalog Number	T
		474790,(October 15, 1999),1-2	
		"Drugs for Selection of Genetic Markers Reagents for positive and negative	
		selection of Genes involved in Nucleotide Metabolism", Calbiochem, (March	
		2002), 6 pgs.	
-		"EPA; 20:5 ω-3; 5,8, 11, 14, 17-Eicosapentaenoic Acid", Calbiochem,	
	1	Eicosapentaenoic Acid, Catalog Number 324875,(December 7, 1998),1-2	
		"Epoxomicin- a potent and selective proteasome inhibitor", Affiniti Research	Т
		Products Limited, 2 pages	
		"International Search Report for corresponding PCT Application No.	
		PCT/US2004/009950", (Attorney Docket No. 875.085WO1),8 pgs.	
		"LDP-341", Millennium Pharmaceuticals,	T
		http://www.biospace.com/ct/detail.cfm?ClinicallD=266404,1 page	
		"Mevinolin; MK-803", Calbiochem, Lovastatin, Catalolg Number 438185,(June	T
		29, 2001),1-2	
		"MK-733", Calbiochem, Simvastatin, Catalog Number 567020,(October 25,	$\top$
		2001),2	
		"Polymer Vectors Endosomal release and cytoplasmic delivery", Endosomal	Τ
		Release, http://web.bham.ac.uk/can4psd4/nonviral/endosome.html,(June 3,	
		2001),1	
		"Product Data Sheet", Moravek Biochemicals, Inc., M-1535, Ritonavir, (July 12,	Τ
		2001),1 page	
		"Product Information", Sigma, Cyclosporin A, Sigma Product No.	
		C3662,(October 28, 1996),3 pages	
		"Product Information", Sigma, Bleomycin Sulfate, Sigma Prod. No.	Т
		B5507,(November 25, 1996),2 pages	
		"Proteasome Inhibitors", Peptides International, Inc., (April 16, 2001),1-2	T
<del></del>		"Tannic Acid, A.C.S. reagent", Sigma, www.sigma-	T
		aldrich.com/sacatolog.nsf/productlookup/Aldrich403040?OpenDocument,1 pg.	

Kevin K. Hill

**EXAMINER** 

PTO/SB/084(10:01)
Approved for use Drough 10/31/2002, 08:08 851-0001
US Paters & Trademark Ottos: U.B. DEPARTMENT OF COLOGISCE

Substitute for form 1449APTO INFORMATION DISCLOSURE	Complete if Known	
STATEMENT BY APPLICANT	Application Number	10/815,557
(Use as many sheets as necessary)	Filing Date	March 31, 2004
	First Named Inventor	Engelhardt, John
	Group Art Unit	1653
	Examiner Name	Unknown
Sheet 3 of 16	Attorney Docket No: 8	375.085US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		ADAMS, JULIAN, et al., "Chapter 28. Novel Inhibitors of the Proteasome and	
		Their Theraputic Use in Inflammation", Annual Reports in Medicinal Chemistry,	
		Academic Press, Inc.,(1996),279-288	
		ADAMS, JULIAN, "Proteasome inhibition: a novel approach to cancer therapy", Trends in Molecular Medicine, 8(4), (2002),S49-S54	
	ļ	ALBERTS, BRUCE, et al., "Molecular Biology of the Cell", 3rd edition,	
t		(1994),618-626	
		ALEXANDER, IAN E., et al., "DNA-Damaging Agents Greatly Increase the	1
		Transduction of Nondividing Cells by Adeno-Associated Virus Vectors", <u>Journal of Virology</u> , 68(12), (December 1994),8282-8287	
	<del> </del>	ALEXANDER, I E., et al., "Effects of Gamma Irradiation on the Transduction of	<del>                                     </del>
	1	Dividing and Nondviding Cells in Brain and Muscle of Rats by Adeno-Associated	
		Virus Vectors", Human Gene Therapy, 7(7), (May 1, 1996),841-850	
	ļ	ANDRE, PATRICE, et al., "An inhibitor of HIV-1 protease modulates proteasome	İ
		activity, antigen presentation, and T cell responses", Proc. National Academy of	1
		Science USA, vol. 95, (October 1998),13120-13124	<u> </u>
		ARCAMONE, F M., "From the Pigments of the Actinomycetes to Third	
	1	Generation Antitumor Anthracyclines", Biochimie (Paris), 80(3), (March	
		1998),201-206	-
		BANERJEE, D., et al., "The Treatment of Respiratory Pseudomonas Infection in	
		Cystic Fibrosis: What Drug and Which Way?", <u>Drugs, 60(5)</u> , (Abstract	
		Only),(November 2000),1 pg.	-
	1	BANK, U., "Review: Peptidases and Peptidase Inhibitors in the Pathogenesis	1
		of Diseases", Cellular Peptidases in Immune Functions and Diseases 2, (Edited	1
		by Jurgen Langner, et al., Kluwer Academic / Plenum Publishers),(2000),349-	
		BARTLETT, JEFFREY S., et al., "Infectious entry pathway of adeno-associated	
	1	virus and adeno-associated virus vectors", Journal of Virology, 74(6), (March	
		2000),2777-2785	
		BARTLETT, J S., et al., "Targeted adeno-associated virus vector transduction of	
		nonpermissive cells mediated by a bispecific F(ab'y) <sub>2</sub> antibody", Nature	
		Biotechnology, 17, (1999),pp. 181-186	
		BASAK, S, et al., "Infectious Entry Pathways for Canine Parvovirus", Virology,	
	ļ	186(2), (February 1992),368-376	
		BERNS, K. I., et al., "Biology of Adeno-associated Virus", In: Current Topics in	1
		Microbiology and Immunology, 218, Springer-Verlag, Berlin: R.W. Compans, et	1
		al., (Eds.),(1996),pp. 1-23	
	<del> </del>	BERNS, K. I., "Parvovirus Replication", Microbiological Reviews, 54 (3), (Sept.	
		1990),pp. 316-329	}

Kevin K. Hill

DATE CONSIDERED May 8, 2007

PTC/SB/084(10-01)
Approved for use through 10/31/2002, CMB 651-0001
US Paters & Trademark Office, U.S., DEPARTMENT OF CONGENCE

Substitute for form 1449APTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	<b>Application Number</b>	10/815,557
(Use as many sheats as necessary)	Filing Date	March 31, 2004
	First Named Inventor	Engelhardt, John
	Group Art Unit	1653
	Examiner Name	Unknown
Sheet 4 of 16	Attorney Docket No: 8	375.085US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner initials*	Cite No '	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		BIES, J., et al., "Oncogenic activation of c-Myb by Carboxyl-Terminal truncation	
		leads to Decreased Proteolysis by the Ubiquitin-26S proteasome pathway",	
		Oncogene, 14(2), (Abstract Only),(January 16, 1997),1 pg.	l .
		BOKKALA, SHAILA, et al., "Angiotensin II-induced Down-regulation of Inositol	
		Trisphosphate Receptors in WB Rat Liver Epithelial Cells", Journal of Biological	
		Chemistry, 272(19), (May 9, 1997),12454-12461	
		BONACORSI, STEPHANE, et al., "Comparative In Vitro Activities of	
		Meropenem, Impenem, Temocillin, Piperacillin, and Ceftazidime in Combination	i
		with Tobramycin, Rifampin, or Ciprofloxacin against Burkholderia cepacia	1
		Isolates from Patients with Cystic Fibrosis", Antimicrobial Agents and	l
		<u>Chemotherapy, 43(2), (February 1999),213-217</u>	<u> </u>
		BRAND, STEPHEN, et al., "Role of the Proteasome in Rat Indomethacin-	
		Induced Gastropathy", Gastroenterology, 116(4) (1999),865-873	<u> </u>
	ĺ	BRAVO, LAURA, "Polyphenois: Chemistry, Dietary Sources, Metabolism and	1
		Nutritional Significance", Nutrition Reviews, 56(11), (November 1998),317-333	ļ
		BRÖTZ, H., "The Lantibiotic Mersacidin Inhibits Peptidoglycan Biosynthesis	
		and the Level of Transglycosylation", Eur. J. Biochem., 246(1), (1997),193-199	ļ
		BUGG, C., et al., "SRI6975 Increases Adenovirus Mediated Gene Transfer	
		Through the Apical Surface of Polarized MDCK Cell Monolayers", Cystic Fibrosis	
	ļ	Foundation: 2000 North American CF Conference, (November 2000),1	
:	İ	CANTIN, ANDRE M., et al., "Aerosolized Prolastin Suppresses Bacterial	ļ
	1	Proliferation in a Model of Chronic Pseudomonas aeruginosa Lung Infection",	
		American Journal of Respiratory and Critical Care Medicine, vol. 160,	
	ļ	(1999),1130-1135	<b></b>
		CHU, Q, et al., "Binding and uptake of Cationic Lipid: pDNA Complexes by	1
		Polarized Airway Epithelial Cells", Human Gene Therapy, 10, (1999),pp. 25-36	-
		CHUNG, KING-THOM, et al., "Tannis and Human Health: A Review", Critical	
	ļ	Reviews in Food Science and Nutrition, 38(6), (1998),421-464	-
	-	CONRAD, C. K., et al., "Safety of single-dose administration of an adeno-	
		associated virus (AAV)-CFTR vector in the primate lung", Gene Therapy, 3(8),	
		(August 1996),658-668	<del> </del>
		COONROD, A, et al., "On the mechanism of DNA transfection: efficient gene	
	<b>!</b>	transfer without viruses", Gene Therapy, 4, (1997),pp. 1313-1321	
	}	CROYLE, MARIA, et al., "Development of Novel Formulations that Enhance	
		Adenoviral-Mediated Gene Expression in the Lung in Vitro and in Vivo",	
		Molecular Therapy, vol. 4, no. 1, (July 2001),22-28	
		DESAI, SHYAMAL, et al., "Ubiquitin-dependent Destruction of Topoisomerase I	
		Is Stimulated by the Antitumor Drug Camptothecin", <u>Journal of Biological</u> Chamieta, 272(39) (September 36, 1997) 24159-24164	
	L	Chemistry, 272(39), (September 26, 1997),24159-24164	ــــــــــــــــــــــــــــــــــــــ

Kevin K. Hill

DATE CONSIDERED May 8, 2007

Substitute for form 1449APTO INFORMATION DISCLOSURE	Complete if Known	
STATEMENT BY APPLICANT	Application Number	10/815,557
(Use as many sheats as necessary)	Filing Date	March 31, 2004
	First Named Inventor	Engelhardt, John
	Group Art Unit	1653
	Examiner Name	Unknown
Sheet 5 of 16	Attorney Docket No: 8	375.085US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Tr
		DIETRICH, CORNELIA, et al., "p53-Dependent cell cycle arrest induced by N-	
		acetyl-L-leucinyl-L -leucinyl-L-norleucinal in platelet-derived growth factor-	
		stimulated human fibroblasts", Proc. of the Nat'l Academy of Sciences of the US,	
		93(20) (1996),10815-10819	
		DING, WEI, et al., "Proteasome Inhibitor LLnL (MG101) Augments AAV5	
	:	Transduction in Polarized Human Airway Epithelia", American Society of Gene	
		<u>Therapy</u> , Abstracts of Scientific Presentations –(Abstract No. 571),(June 5, 2002),1 pg.	
		DING, W., et al., "Second-Strand Genome Conversion of Adeno-Associated	
		Virus Type 2 (AAV-2) and AAV-5 is Not Rate Limiting Following Apical Infection	1
		of Polarized Human Airway Epithelia", <u>Journal of Virology</u> , <u>77(13)</u> , (2003),7361-7366	
· · · · · · · · · · · · · · · · · · ·	<del>                                     </del>	DISHART, KATE, et al., "Recombinant Adeno-Associated Virus-2 as a	
		Candidate Gene Delivery Vector for Vein Grafts", American Society of Gene	1
		Therapy, Abstracts of Scientific Presentations, (Abstract No. 1107),(June 5,	
		2002),1 page	
		DONALDSON, S. H., et al., "Regulation of the Epithelial Sodium Channel by	
ł		Serine Proteases in Human Airways", The Journal of Biological Chemistry,	
· ·		277(10), (2002),8338-8345	
		DOUAR, AM., et al., "Intracellular Trafficking of Adeno-Associated Virus	1
		Vectors: Routing to the Late Endosomal Compartment and Proteasome	1
		Degration", Journal of Virology, 75(4), (2001),1824-1833	
		DUAN, D., et al., "A New Dual-Vector Approach to Enhance Recombinant	
		Adeno-Associated Virus-Mediated Gene Expression Through Intermolecular cis	1
		Activation", Nature Medicine, 6(5), (2000),595-598	<u> </u>
		DUAN, D., et al., "Chapter 15: Trans-Splicing Vectors Expand the Packaging	
		Limits of Adeno-Associated Virus for Gene Therapy Applications", Methods in	1
	i .	Molecular Medicine, Vol. 76: Viral Vectors for Gene Therapy: Methods and	1
		Protocols, (2003),287-307	
		DUAN, D., et al., "Chapter 3 - Adeno-Associated Virus", In: Lung Biology in	1
		Health and Disease, Vol. 169 - Gene Therapy in Lung Disease, Albelda, S. M.,	
	1	Editor, Marcel Dekker, Inc.,(2002),51-92	4
		DUAN, D., et al., "Chapter 3 - Dual Vector Expansion of the Recombinant AAV	
		Packaging Capacity", In: Methods in Molecular Biology, Vol. 219: Cardiac Cell	
		and Gene Transfer, Metzger, J. M., Editor, Human Press, Inc., Totowa,	1
	<u></u>	NJ.(2003),29-51	1
		DUAN, D, et al., "Circular Intermediates of Recombinant Adeno-Associated	1
		Virus Have Defined Structural Characteristics Responsible for Long-Term	1
		Episomal Persistence in Muscle Tissue", Journal of Virology, 72(11).	
L		(1998),8568-8577	

Kevin K. Hill

**EXAMINER** 

PTO/SB/084(10-01)
Approved for use through 10/31/2002, 0MB 851-0031
US Patent & Tretement Office: U.S. OEPARTMENT OF COMCERCE

Substitute for form 1449A/PTO	Complete if Known	regulared to respond to a collection of information unless it contains a valid QAM) control number
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	10/815,557
(Use as many sheets as necessary)	Filing Date	March 31, 2004
	First Named Inventor	Engelhardt, John
	Group Art Unit	1653
	Examiner Name	Unknown
Sheet 6 of 16	Attorney Docket No: 8	375.085US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T,
		DUAN, D., et al., "Consequences of DNA-Dependent Protein Kinase Catalytic	
		Subunit Deficiency on Recombinant Adeno-Associated Virus Genome	1
		Circularization and Heterodimerization in Muscle Tissue", Journal of Virology,	}
		77(8), (2003),4751-4759	İ
		DUAN, DONGSHENG, et al., "Dynamin is required for recombinant adeno-	1
		associated virus type 2 infection", Journal of Virology, 73(12), (December	ł
		1999),10371-10376	
		DUAN, D., et al., "Endosomal processing limits gene transfer to polarized airway	Т
		epithelia by adeno-associated virus", Journal of Clinical Investigation, 105,	
		(June, 2000),1573-1587	
	<del></del>	DUAN, D., et al., "Enhancement of Muscle Gene Delivery With Pseudotyped	1
•		Adeno-Associated Virus Type 5 Correlates With Myoblast Differentiation",	1
		Journal of Virology, 75(16), (2001),7662-7671	1
	<b></b>	DUAN, D., et al., "Expanding AAV Packaging Capacity With <i>Trans</i> -splicing or	$\vdash$
		Overlapping Vectors: A Quantitative Comparison", Molecular Therapy, 4(4),	
		(2001),383-391	
		DUAN, D., "Formation of Adeno-Associated Virus Circular Genomes is	$\vdash$
		Differentially Regulated by Adenovirus E4 ORF6 and E2a Gene Expression",	1
		Journal of Virology, 73(1), (Jan. 1999),161-169	
		DUAN, D., "Polarity Influences the Efficiency of Recombinant Adenoassociated	✝
		Virus Infection in Differentiated Airway Epithelia", <u>Human Gene Therapy</u> , 9,	
		(Dec. 10, 1998),2761-2776	
		DUAN, D, et al., "Response to "Polarity Influences the Efficiency of	Т
		Recombinant Adenoassociated Virus Infection in Differentiated Airway	
		Epithelia", Human Gene Therapy, 10, (1999),pp. 1553-1557	1
		DUAN, DONGSHENG, et al., "Structural Analysis of adeno-associated virus	+
	1	transduction circular intermediates", Virology, 261(1), (Aug. 1999),8-14	ı
		DUAN, DONGSHENG, et al., "Structural and functional heterogeneity of	十
		intregrated recombinant AAV genomes", Virus Research, 48 (1), (Jan. 1997),pp.	ł
		41-56	1
	<del> </del>	ELLIOTT, P J., et al., "Recent Advances in Understanding Proteasome	+
		Function", Current Opinion in Drug Discovery and Development, 5 (2), ISSN:	
		1367-6733,(1999),484-490	
	<del> </del>	ENGELHARDT, J. F., et al., "Direct Gene Transfer of Human CFTR Into Human	1
		Bronchial Epithelia of Xenografts With E1-Deleted Adenoviruses", Nature	
		Genetics, 4, (1993),27-34	
	<del> </del>	ENGELHARDT, J. F., "The Lung as a Metabolic Factory for Gene Therapy",	+
		The Journal of Clinical Investigation, 110(4), (2002),429-432	
		EVERETT, R D., et al., "A viral activator of gene expression functions via the	+
		ubiquitin-proteasome pathway", The EMBO Journal, 17 (24), (1998),pp. 7161-	
		7169	

EXAMINER Kevin K. Hill

PTO/SB/084(10-01)
Approved for use through 10/31/2022, OMB 651-0031
US Patent & Trademan Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) ,	Complete if Known		
	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 7 of 16	Attorney Docket No: 8	375.085US1	

Examiner	Cite	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the ltem	Τ²
Initials*	No 1	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Ĺ
		FASBENDER, AL, et al., "Complexes of adenovirus with polycationic polymers	
		and cationic lipids increase the efficiency of gene transfer in viro and in vivo",	
		The Journal of Biological Chemistry, 272 (10), (March 7, 1997),6479-6489	
		FAYADAT, LAURENCE, et al., "Degradation of Human Thyroperoxidase in the	
		Endoplasmic Reticulum Involves Two Different Pathways Depending on the	
		Folding State of the Protein", Journal of Biological Chemistry, 275(21), (May 26,	l
		2000),15948-15954	
		FENTEANY, G., et al., "Inhibition of Proteasome Activities and Subunit-Specific	
		Amino-Terminal Threonine Modification by Lactacystin", Science, 268, (1995),	l
		726-731	L
		FENTEANY, GABRIEL, et al., "Lactacystin, Proteasome Function, and Cell	1
		Fate", Journal of Biological Chemistry, 273(15), (April 10, 1998),8545-8548	Ļ
		FERRARI, F K., et al., "Second-Strand Synthesis Is a Rate-Limiting Step for	1
		Efficient Transduction by Recombinant Adeno-Associated Virus Vectors",	İ
		Journal of Virology, 70(5), (1996),3227-3234	L
		FIGUEIREDO-PEREIRA, MARIA E., et al., "The antitumor drug aclacinomycin A,	
		which inhibits the degradation of ubiquitinated proteins, shows selectivity for the	
		chymotrypsin-like activity of the bovine pituitary 20 S proteasome", Journal of	
	ļ. ,	Biological Chemistry, 271(28), (July 12, 1996),16455-16459	
		FISHER, KRISHNA, et al., "Recombinant adeno-associated virus for muscle	
	ļ	directed gene therapy", Nature Medicine, 3 (3), (March 1997),pp. 306-312	╀
		FISHER, K J., et al., "Transduction with recombinant adeno-associated virus for	l
	:	gene therapy is limited by leading-strand synthesis", <u>Journal of Virology, 70(1)</u> ,	
		(Jan., 1996),520-532	+
		FLOTTE, T. R., et al., "Adeno-Associated Virus Vector Gene Expression Occurs	
		in Nondividing Cells in the Absence of Vector DNA Integration", American	
<u>:</u> _	ļ	Journal of Respiratory Cell and Molecular Biology, 11, (1994),pp. 517-521	╀
		FLOTTE, T. R., et al., "Chapter 40 - Adeno-Associated Viral Vectors for CF	
•		Gene Therapy", In: Methods in Molecular Medicine, 70, (2002),599-608  GABIZON, ALBERTO, "Long-circulating liposomes for drug delivery in cancer	╀
		therapy: a review of biodistribution studies in tumor-bearing animals", Advanced	1
		Drug Delivery Reviews, (1997),337-344	1
	<del> </del>	GABIZON, ALBERTO, et al., "Preclinical Studies with Doxorubicin Encapsulated	╁
		in Polyethyleneglycol-Coated Liposomes", <u>Journal of Liposome Research</u> , 3(3),	ļ
		(1993),517-528	Ì
·	· ·	GARBER, KEN, "Taking Garbage In, Taking Cancer Out?", Science, 295,	+
		(January 25, 2002),612-613	
		GOLDBERG, A L., et al., "New insights into proteasome function: from	
		archaebacteria to drug development", Chemistry & Biology, 2(8), (1995), 503-	
		508	$\perp$

PTO/SB/084(10-01)
Approved for use through 10/31/2002, CAS 651-0001
US Patent & Tradement Office: U.S. DEPARTMENT OF CONDERCE

	Under the Peperwork Reduction Act of 1995, no persons are	required to respond to a collection of information unless it contains a valid OMB control number	
Substitute for form 1449APTO	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/815,557	
(Use as many sheets as necessary)	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 8 of 16	Attorney Docket No: 8	375.085US1	

	OTHER	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	7
		GOTTLIEB, T A., et al., "Actin Microfilaments Play a Critical Role in Endocytosis	
		at the Apical but not the Basolateral Surface of Polarized Epithelial Cells", The	
		Journal of Cell Biology, 120 (3), (1993), 695-710	
		GRUCHALA, MARCIN, et al., "Adeno-Associated Virus-Mediated Gene Transfer into Normal Rabbit Arteries. Assessment of the Tie and CMV Promoters and the	
		Antiproteasome Treatment with MG-132", American Society of Gene Therapy,	
ì		Abstracts of Scientific Presentations, (Abstract No. 1110), (June 5, 2002),1 page	
	<b>.</b>	HALBERT, C. L., "Transduction by Adeno-Associated Virus Vectors in the	
	Ì	Rabbit Airway: Efficiency, Persistence, and Readministration", Journal of	
	i	Virology, 71(8), (Aug. 1997),pp. 5932-5941	
		HANSEN, J., et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer:	
		Altered Endocytic Processing Enhances Transduction Efficiency in Murine	
		Fibroblasts", Journal of Virology, 75(9), (2001),4080-4090	
		HANSEN, J., et al., "Impaired Intracellular Trafficking of Adeno-Associated Virus	
		Type 2 Vectors Limits Efficient Transduction of Murine Fibroblasts", <u>Journal of</u>	
		Virology, 74(2), (2000),992-996	
		HASEGAWA, S., et al., "Microtubule involvement in the intracellular dynamics for	
		gene transfection mediated by cationic liposomes", Gene Therapy, 8,	
		(2001),1669-1673	
		HONG, J., et al., "Identification of SRI6975, A Compound that Enhances	
1		Adenovirus-Mediated Gene Expression in Polarized Epithelial Cells", Cystic	
Ì		Fibrosis Foundation: 2000 North American CF Conference, (November 2000), 1-2	
	<del> </del>	HOSSEINI, HASSAN, et al., "Protection against experimental autoimmune	
	}	encephalomyelitis by a proteasome modulator", Journal of Neuroimmunology,	
		188, (2001),233-244	
	T	HSU, A., et al., "Ritonavir. Clinical pharmacokinetics and interactions with other	
	Ì	anti-HIV agents", Clin Pharmacokinet, 35(6), (Abstract Only),(December 1998),	
		1 pg.	
		HUANG, L., et al., "Efficient lipofection with cisplatin-resistant human tumor	
		cells", Cancer Gene Therapy, 3(2), (1996),107-112	
		IQBAL, MOHAMED, et al., "Potent Inhibitors of Proteasome", <u>Journal of</u>	
<u> </u>	<b></b>	Medicinal Chemistry, 38(13), (1995),2276-2277	<del> </del>
		ITANI, O. A., et al., "Cycloheximide Increases Glucocorticoid-Stimulated alpha-	[
1		ENaC mRNA in Collecting Duct Cells by p38 MAPK-dependent Pathway", Am. J.	
<u> </u>	+	Physiol. Renal Physiol., 284, (2002),F778-F787  JENSEN, T J., et al., "Multiple Proteolytic Systems, Including the Proteasome,	<del>                                     </del>
	1	Contribute to CFTR Processing", Cell, 83, (1995),pp. 129-135	
	+	JIANG, Q., et al., "Cellular Heterogeneity of CFTR Expression and Function in	
		the Lung: Implications for Gene Therapy of Cystic Fibrosis", European Journal of	]
		Human Genetics, 6, (January, 1998), 12-31	

EXAMINER Kevin K. Hill

PTO/SB/054(10-01)
Approved for use Dyough 10/31/2002, OMB 651-0001
US Patent & Tradement Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete if Known		
	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 9 of 16	Attorney Docket No: 8	375.085US1	

		R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		KAPLAN, JOHANNE M., et al., "Potentiation of gene transfer to the mouse lung	1
•	· ·	by complexes of adenvirus vector and polycations improves therapeutic	
	· .	potential", <u>Human Gene Therapy, 9(10),</u> (July 1, 1998),1469-1479	<u></u>
		KAZI, A., et al., "Inhibition of the Proteasome Activity, a Novel Mechanism	ì
		Associated with the Tumor Cell Apoptosis-Inducing Ability of Genistein",	
		Biochemical Pharmacology, 66, (2003),965-976	ļ
		KESSLER, P., et al., "Sodium Butyrate Greatly Enhances the efficiency of Viral	ļ
		Transduction in Adult Ventricular Cardiomyocytes by Adeno-associated Viral	
		Vectors", Circulation 92(8), (Abstract Only), (October 15, 1995),296	
	1	KIM, KYUNG BO, et al., "Proteasome Inhibition by the Natural Products	
		Epoxomicin and Dihydroeponemycin: Insights into Specificity and Potency",	
		Bioorganic & Medicinal Chemistry Letters, (1999),3335-3340	<b></b>
		KIM, KOANHOI, "Proteasome Inhibitors Sensitize Human Vascular Smooth	
		Muscle Cells to Fas (CD95) - Mediated Death", Biochemical and Biophysical	
		Research Communications, 281(2), (2001),305-310	<u> </u>
		KIYOMIYA, KEN-ICHI, et al., "Mechanism of Specific Nuclear Transport of	İ
		Adriamycin: The Mode of Nuclear Translocation of Adriamycin-Proteasome	
		Complex", Cancer Research, (March 15, 2001),2467-2471	<u> </u>
		KIYOMIYA, K., et al., "The role of the proteasome in apoptosis induced by	
		anthracycline anticancer agents", Int. J. Oncol., 20(6), (Abstract Only),(June	
		2002), 1 pg.	
		KIYOMIYA, KEN-ICHI, et al., "The Role of the Proteasome in apoptosis induced	1
		by anthracycline anticancer agents", <u>International Journal of Oncology, 20 (6)</u>	Ì
		ISSN: 1019-6439,(June 2002),1205-1209	<del> </del>
		KLOETZEL, P M., "The Proteasome system: a neglected tool for improvement	}
		of novel therapeutic strategies?", Gene Therapy, 5, (1998), 1297-1298	<del> </del>
		KUMAR, GITA, "Side-stepping the side effects", BioCentury, The Bernstein	
	<del> </del>	Report on BioBusiness, (December 17, 2001), 1 pg.	<del> </del>
		LEBKOWSKI, J., "Adeno-Associated Virus: a Vector System for Efficient	
		Introduction and Integration of DNA into a Variety of Mammalian Cell Types", Molecular and Cellular Biology, 8(10), (October 1988),3988-3996	
	<del> </del>	LEE, SANG GOO , et al., "Enhancement of adenoviral transduction with	+
		polycationic liposomes in vivo", Cancer Gene Therapy, 7(10), (2000),1329-1335	}
<del></del>	<del> </del>	LEE, D. H., "Proteasome Inhibitors: Valuable New Tools For Cell Biologists",	╁┈
		Trends in Cell Biology, 8, (October 1998), 397-403	
	<del> </del>	LEE, DO HEE, et al., "Selective Inhibitors of the Proteasome-dependent and	+
		Vacuolar Pathways of Protein Degradation in Saccharomyces cerevisiae",	
		Journal of Biological Chemistry, (November 1, 1996),27280-27284	
	ļ	LEE, DO HEE, et al., "Chapter 10 - The Proteasome Inhibitors and Their Uses",	1
		Proteasomes: The World of Regulatory Proteolysis, (2000),154-175	
	1	1 Total Sources. The World of Tragalatory Trateory and Level 1, 104 170	<del>ــــــــــــــــــــــــــــــــــــ</del>

Kevin K. Hill

**EXAMINER** 

PTO/SB/054(10-01)
Approved for use through 10/31/2002, OMB 651-0031
US Paser & Tredeman Officer U.S. GEPARTMENT OF COLOGERCE

Substitute for form 1449A/PTO INFORMATION DISCLOSURE	Under the Peparwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it contains a valid CMRI control number Compilete If Known		
Sheet 10 of 16	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
	Attorney Docket No: 8	375.085US1	

	OTHER	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-Issue number(s), publisher, city and/or country where published.	Ţ².
		LIANG, E., et al., "Oligonucleotide delivery: a cellular prospective", <u>Pharmazie</u> , 54(8), (Aug. 1999), 559-566	
		LU, WEI, et al., "HIV protease inhibitors restore impaired T-cell proliferative response in vivo and in vitro: a viral-suppression-independent mechanism", Blood, 96(1), (July 1, 2000), 250-258	
		LUO, HONGYU, et al., "A Proteasome Inhibitor Effectively Prevents Mouse Heart Allograft Rejection", Transplantation, 72(2), (July 27, 2001),196-202	
		MAH, C. et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Role of Epidermal Growth Factor Receptor Protein Tyrosine Kinase in Transgene Expression", Journal of Virology, 72(12), (1998),pp. 9835-9843	
	<del>,</del>	MAITRA, R., et al., "Increased Functional Cell Surface Expression of CFTR and ΔF508-CFTR by the Anthracycline doxorubicin", <u>Am. J. Physiol. Cell Physiol.</u> 280, (May, 2001),C1031-C1037	
		MALIK, B., et al., "ENaC Degradation in A6 Cells by the Ubiquitin-Proteosome Proteolytic Pathway", The Journal of Biological Chemistry, 276(16), (Apr. 20, 2001),12903-12910	
		MASTROIANNI, CLAUDIO M., et al., "Ex Vivo and In Vitro Effect of Human Immunodeficiency Virus Protease Inhibitors on Neutrophil Apoptosis", <u>Journal of Infectious Diseases (182)</u> , (November 2000),1536-1539	
		MATTSSON, KARIN, et al., "Proteins associated with the promyelocytic leukemia gene product (PML)-containing nuclear body move to the nucleolus upon inhibition of proteaseome-dependent protein degradation", Proc. Natl. Acad. Sci., USA, 98(3), (January 30, 2001),1012-1017	
<u> </u>	\ <u></u>	MCAULIFFE, O., et al., "Lantibiotics: Structure, Biosynthesis and Mode of Action", FEMS Microbiology Reviews, 25(3), (2001),285-308	
		MENG, LIHAO, et al., "Eponemycin Exerts Its Antitumor Effect through the Inhibition of Proteasome Function", Cancer Research, 59, (June 15, 1999), 2798-2801	
		MENG, L., et al., "Epoxomicin, a potent and selective proteasome inhibitor, exhibits <i>in vivo</i> antiinflammatory activity", <u>Proc. Natl. Acad. Sci. USA, 96(18)</u> , (August 31, 1999),10403-10408	
		MEYER, STEPHANIE, et al., "Cyclosporine A is an uncompetitive inhibitor of proteasome activity and prevents NF-kB activation", Federation of European Biochemical Societies, (1997),354-358	
		MOSNAIM, ARON, et al., "Degradation Kinetics of Leucine <sup>5</sup> -Enkephalin by Plasma Samples from Healthy Controls and Various Patient Populations: In Vitro Drug Effects", American Journal of Therapeutics, vol. 7, (2000),185-194	
		NAM, SANGKIL, et al., "Tannic Acid Potently Inhibits Tumor Cell Proteasome Activity, Increases p27 and Bax Expression, and Induces G, Arrest and Apoptosis", Cancer Epidemiology, Biomarkers & Prevention, 10, (October, 2001),1083-1088	

Kevin K. Hill

**EXAMINER** 

PTO/SE/084(10:01)
Approved for use through 10/31/2002, 0349 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF CONDURACE

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete il Known		
	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 11 of 16	Attorney Docket No: 8	375.085US1	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No '	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-lasue number(s), publisher, city and/or country where published.	Į,
		NEPKA, CHARITINI, et al., "Chemopreventive activity of very low dose dietary	
		tannic acid administration in hepatoma bearing C3H male mice", Cancer Letters,	}
		vol. 141, (1999),57-62	L
		NEPKA, CH., et al., "Tannins, xenobiotic metabolism and cancer chemo-	1
		prevention in experimental animals", European Journal of Drug Metabolism and	1
		Pharmacokinetics, 24(2), (1999), 183-189	
		NIELSEN, J., et al., "Spironolactone-Mediated Downregulation of the Epithelial	
		Sodium Channel (eNaC) in Rat Kidney", FASEB Journal, 15(1) (Abstracts Part I).	
	0	Abstract No. 393.11,(2001), A432	
		OBIN, M., et al., "Neurite outgrowth in PC12 cells. Distinguishing the roles of	
		ubiquitylation and ubiquitin-dependent proteolysis", Journal of Biological	
		Chemistry, 274(17), (April 23, 1999),11789-11795	ļ
		PALOMBELLA, VITO, et al., "Role of the proteasome and NF-кВ in	
		streptococcal cell wall-induced polyarthritis", Proc. Natl. Acad. Sci. USA, 95,	
		(December 1998),15671-15676	<b>_</b>
		PAOLINI, ROSSELLA, et al., "Ubiquitination and degradation of Syk and ZAP-	
		70 protein tyrosine kinases in human NK cells upon CD16 engagement", Proc.	
	<del></del>	Natl. Acad. USA, 98(17), (August 14, 2001),9611-9616  PARKER, J. S., et al., "Cellular Uptake and Infection by Canine Parvovirus	<u> </u>
		Involves Rapid Dynamin-Regulated Clathrin-Mediated Endocytosis, Followed by	
		Slower Intracellular Trafficking", <u>Journal of Virology</u> , 74(4), (2000),1919-1930	ļ
		PETROV, VICTOR, et al., "Effect of Protease Inhibitors on Angiotensin-	<del> </del>
		Converting Enzyme Activity in Human T-Lymphocytes", American Journal of	ŀ
		Hypertension, 13(5), (May 2000),535-539	
		PICCININI, M., et al., "The human 26S proteasome is a target of antiretroviral	
		agents", AIDS, 16(5), (Abstract Only),(March 29, 2002), 1 pg.	
		PICKLES, R J., et al., "Limited Entry of Adenovirus Vectors into Well-	
		Differentiated Airway Epithelium Is Responsible for Inefficient Gene Transfer",	
		Journal of Virology, 72 (7), (1998),pp. 6014-6023	
		PRINCIOTTA, MICHAEL F., et al., "Cells adapted to the proteasome inhibitor 4-	1
		hydroxy-5-iodo-3-nitrophenylacetyl-Leu-Leu-leucinal-vinyl sulfone require	
		enzymatically active proteasomes for continued survival", Proc. Acad. Sci. USA,	
		98(2), (January 16, 2001),513-518	
		PRYDZ, K, et al., "Effects of Brefeldin A on Endocytosis, and Transport to the	
		Golgi Complex in Polarized MDCK Cells", The Journal of Cell Biology, 119 (2),	
		(1992), 259-272	
		PUTTARAJU, M., et al., "Spliceosome-mediated RNA trans-splicing as a tool for	
		gene therapy", Nature Biotechnology, 17 (3), (March 1999), 246-252	<u> </u>

Kevin K. Hill

Substitute for form 1449A/PTO	Complete If Known	regulard to respond to a collection of information unless it contains a valid GMB control number
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/815,557
(Use as many sheets as necessary)	Filing Date	March 31, 2004
	First Named Inventor	Engelhardt, John
	Group Art Unit	1653
	Examiner Name	Unknown
Sheet 12 of 16	Attorney Docket No: 8	375.085US1

		R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1,
		QING, K., et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer:	
		Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D	ł
		Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro	
		and Murine Tissues In Vivo", <u>Journal of Virology</u> , 72 (2), (Feb. 1998),pp. 1593-1599	
<del>``</del>		QING, K., et al., "Human fibroblast growth factor receptor 1 is a co-receptor for	
		infection by adeno-associated virus 2", Nature Medicine, 5 (1), (Jan. 1999),pp. 71-77	
		QING, K., "Role of tyrosine phosphorylation of a cellular protein in adeno-	
		associated virus 2-mediated transgene expression", Proc. Natl. Acad. Sci. USA,	1
		94, (September, 1997), 10879-10884	
		RAO, SHARMILA, et al., "Lovastatin-mediated G <sub>1</sub> arrest is through inhibition of	
		the proteasome, independent of hydroxymethyl glutaryl-CoA reductase", Proc.	ļ
		Natl. Acad. Sci. USA, 96, (July 1999),7797-7802	L
		RENDAHL, K. G., et al., "Regulation of Gene Expression in vivo Following	١
		Transduction by Two Separate rAAv Vectors", Nature Biotechnology, 16,	l
		(1998),757-761	<u> </u>
		RICHARDS, R. G., et al., "E2-Induced Degradation of Uterine Insulin Receptor	
		Substrate-2: Requirement for an IGF-I-Stimulated, Proteasome-Dependent	
		Pathway", Endocrinology, 142(9), (September 2001), 3842-3849	↓_
		ROCK, K L., et al., "Inhibitors of the Proteasome Block the Degradation of Most	
		Cell Proteins and the Generation of Peptides Presented on MHC Class I	
		Molecules", <u>Cell, 78,</u> (1994), 761-771	_
		RUSSELL, D.W., et al., "DNA synthesis and topoisomerase inhibitors increase transduction by adeno-associated virus vectors", Proc. Natl. Acad. Sci., 92,	
		(1995), 5719-5723	╁
		SANLIOGLU, S, et al., "Cellular redox state alters recombinant adeno-	1
		associated virus transduction through tyrosine phosphatase pathways", Gene	
		Therapy, 6, (1999),pp. 1427-1437	╀
		SANLIOGLU, S., et al., "Endocytosis and Nuclear Traffickling of Adeno-	1
		Associated Virus Type 2 Are Controlled by Rac1 and Phosphatidylinositol-3	1
	ļ	Kinase Activation", Journal of Virology, 74(19), (2000),9184-9196	╁
		SANLIOGLU, S., et al., "Lipopoolysaccharide Induces Rac1-Dependent Reactive	
		Oxygen Species Formation and Coordinates Tumor Necrosis Factor-alpha	1
		Secretion Through IKK Regulation of NF-kB", The Journal of Biological	
		Chemistry, 276(32), (2001),30188-30198	+
		SANLIOGLU, S., et al., "Loss of ATM Function Enhances Recombinant Adeno-	
		Associated Virus Transduction and Integration Through Pathways Similar to UV	
	<u> </u>	Irradiation", Virology, 268, (2000),68-78	┸

DATE CONSIDERED May 8, 2007

PTC/SB/05A(10-01)
Approved for use through 10/31/2002, CAGE 651-0031
US Paters & Trademark Office: U.S. DEPARTMENT OF CONDERCE

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as nocassary)	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 13 of 16	Attorney Docket No: 8	375.085US1	

Examiner	Cite	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item	T <sup>2</sup>
Initials*	No 1	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
		SANLIOGLU, S., et al., "Rate Limiting Steps of AAV Transduction and	-
		Implications for Human Gene Therapy", Current Gene Therapy, 1, (2001),137-	
	•	147	
		SANLIOGLU, S., et al., "Two Independent Molecular Pathways for Recombinant	Γ
		Adeno-Associated Virus Genome Conversion Occur After UV-C and E4orf6	1
		Augmentation of Transduction", Human Gene Therapy, 10(4), (1999),591-602	İ
		SASAKI, T., et al., "Inhibitory Effect of di- and Tripeptidyl Aldehydes on Calpains	
		and Cathepsins", Journal of Enzyme Inhibition, 3(3), (1990),195-201	
		SCHWARTZ, O, et al., "Antiviral Activity of the Proteasome on Incoming Human	T
		Immunodeficiency Virus Type 1", Journal of Virology, 72 (5), (1998), 3845-3850	
		SCHWARTZ, DONALD, et al., "The neutral cysteine protease bleomycin	
		hydrolase is essential for epidermal integrity and bleomycin resistance", Proc.	1
		National Academy of Science USA, vol. 96, (April 1999),4680-4685	
		SCHWARZ, KATRIN, et al., "The Selective Proteasome Inhibitors Lactacystin	†
		and Epoxomicin can be used to either Up- or Down-Regulate Antigen	
,		Presentation at Nontoxic Doses", <u>Journal of Immunology</u> , (2000),6147-6157	1
		SHAH, SHIMUL, et al., "26S Proteasome Inhibition Induces Apoptosis and	+-
		Limits Growth of Human Pancreatic Cancer", <u>Journal of Cellular Biochemistry</u> ,	
		vol. 82, (2001),110-122	
	ļ	SMITH, H., et al., "Effect of a cancer cachectic factor on protein	+
		synthesis/degradation in murine C2C12 myoblasts: modulation by	1
		eicosapentaenoic acid", <u>Cancer Res.</u> , 59(21), (Abstract Only), (November 1999),	
		1 pg.	
		SMITH, ANDREW, et al., "The Role of the Epidermal Growth Factor Receptor in	T
		Recombinant Adeno-Associated Virus Type-2 Mediated Transgene Expression	
		in Lung Epithelial Cells", Molecular Therapy, 5(5), (Abstract No. 568), (May	
		2002), pg. \$186	1
		SON, KYONGHEE, et al., "Exposure of human ovarian carcinoma to cisplatin	1
		transiently sensitizes the tumor cells for liposome-mediated gene transfer", Proc.	1
		Natl. Acad. Sci. USA, 91, (December 1994), 12669-12672	1
		SON, K., et al., "Factors influencing the drug sensitization of human tumor cells	十
		for in situ lipofection", Gene Therapy(3), (1996), 630-634	ı
	<del> </del>	SON, KYONGHEE, et al., "Nitric oxide-mediated tumor cell killing of cisplatin-	T
		based interferon-y gene therapy in murine ovarian carcinoma", Cancer Gene	1
		Therapy, 7(10), (2000),1324-1328	1
	<del>                                     </del>	SPINDLER, B., et al., "Characterization of Early Aldosterone-induced RNAs	十
		identified in A6 Kidney Epithelia", <u>Pfluegers Archiv</u> , Vol. 434, Springer Verlag,	
		Berlin, DE (1997),323-331	

Kevin K. Hill

PTC/SB/084(10-01
Approved for use through 10/31/2002, ONE 651-003
Peters & Tardenark Office U.S. DEPARTMENT OF COMMISSION

Substitute for form 1449APTO	Complete il Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 14 of 16	Attorney Docket No: 8	375.085US1	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		STAUB, O., "Chapter 5 Regulation of ENaC by Interacting Proteins and by	
		Ubiquitination", Current Topics in Membranes, 47 - Amiloride-Sensitive Sodium	
		Channels - Physiology and Functional Diversity, Edited by Dale J. Benos,	1
		Academic Press, Publisher,(1999),65-87	<u> </u>
		STAUB, O., "Regulation of Stability and Functional of the Epithelial Na* Channel	1
		(ENaC) by Ubiquitination", The EMBO Journal, 16(21), (1997),6325-6336	<u> </u>
		STOCKAND, J. D., et al., "Targeted Degradation of the Epithelial Na Channel	
		(ENaC) in Response to PKC Activation of the MAPK 1/2 Cascade", The FASEB	ļ
		Journal, 17(5), Abstracts (Part II), (Abstract No. 585.7),(2003), pg. A913	1
		STOKES, J. B., "Regulation of rENac mRNA by Dietary NaCl and Steroids:	
		Organ, Tissue, and Steroid Heterogeneity", American Journal of Physiology, Cell	1
		Physiology, 274, (1998),C1699-C1707	<u> </u>
		SWINNEY, DAVID C., et al., "Targeting protein ubiquitination for drug discovery.	
		What is in the drug discovery toolbox?", DDT, 6(5), (March, 2001), 244-250	
		TAJIMA, KIMIHISA, et al., "The proteasome inhibitor MG132 promotes .	
		accumulation of the steroidogenic acute regulatory protein (StAR) and	Į.
•		steriodogenesis", Federation of European Biochemical Societies, 490,	
		(January 24, 2001), 59-64	
		TEODORI, L., et al., "Reduction of 1-beta-D-arabinofuranosylcytosine and	
		adriamycin cytotoxicity following cell cycle arrest by anguidine", Cancer Res.,	
	·	41(4), (Abstract Only),(April 1981),1 pg.	l .
		TERAMOTO, S., et al., "Factors influencing adeno-associated virus-mediated	
		gene transfer to human cystic fibrosis airway epithelial cells: comparison with	
		adenovirus vectors", Journal of Virology, 72(11), (Nov., 1998), 8904-8912	
		TWEEDALE, TONY, "[Dioxin-I] Inhibits Estrogen-Induced Breast Cancer Cell	
		Proliferation", Reuters Health, http://lists.essential.org/pipermail/dioxin-l/Week-of-	1
		Mon-2000103/000096.html,(December 1999), 1 pg.	
		VAN KERKHOF, PETER, et al., "Proteasome Inhibitors Block a Late Step in	
		Lysosomal Transport of Selected Membrane but not Soluble Proteins", Molecular	
		Biology of the Cell, vol. 12, (August 2001),2556-2566	
		VIHINEN-RANTA, M, et al., "Intracellular Route of Canine Parvovirus Entry",	
		Journal of Virology, 72(1), (1998), 802-806	
		VILLANI, P., et al., "Antiretrovirals: Simultaneous determination of five protease	
		inhibitors and three nonnucleoside transcriptase inhibitors in human plasma by a	
	ŀ	rapid high-performance liquid chromatography-mass spectrometry assay", The	
		Drug Monit., 23(4), (Abstract Only),(August 2001),1 pg.	
		WALTERS, R.W., et al., "Basolateral localization of fiber receptors limits	
		adenovirus infection from the apical surface of airway epithelia", The Journal of	
		Biological Chemistry, 274(15), (April 9, 1999),10219-10226	

Kevin K. Hill DATE CONSIDERED May 8, 2007

PTO/SB/084 (10-01)
Approved for use through 10/31/2002, OMB 651-0031
US Perer & Tradement Office U.S. DEPARTMENT OF COMMERCE

Substitute for form 1448APTO INFORMATION DISCLOSURE	Complete if Known		
STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	10/815,557	
	Filing Date ·	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653 .	
	Examiner Name	Unknown	
Sheet 15 of 16	Attorney Docket No: 8	375.085US1	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	<u> </u>	WALTERS, R.W., et al., "Incorporation of Adeno-Associated Virus in a Calcium	
		Phosphate Coprecipitate Improves Gene Transfer to Airway Epithelia In Vitro	
		and In Vivo", Journal of Virology, 74 (1), (2000),535-540	<u></u>
		WESTFALL, T. D., et al., "The Ecto-ATPase Inhibitor ARL 67156 Enhances	
		Parasympathetic Neurotransmission in the Guinea-Pig Urinary Bladder",	
		European Journal of Pharmacology, 329, (1997),169-173	
		WHITEHOUSE, ALISON, et al., "Downregulation of Ubiquitin-Dependent	
		Proteolysis by Eicosapentaenoic Acid in Acute Starvation", Biochemical and	
		Biophysical Research Communications, 285(3), (2001),598-602	<u> </u>
		WICKHAM, T J., et al., "Adenovirus targeted to heparan-containing receptors	
		increases its gene delivery efficiency to multiple cell types", Nature	
		Biotechnology, 14, (1996),1570-1573	ļ
		WICKHAM, T J., et al., "Targeted Adenovirus Gene Transfer to Endothelial and	1
		Smooth Muscle Cells by Using Bispecific Antibodies", <u>Journal of Virology</u> , 70	
		<u>(10),</u> (1996), 6831-6838	<u> </u>
		WOESSNER, RICHARD, et al., "Comparison of Three Approaches to	
		Doxorubicin Therapy: Free Doxorubicin, Liposomal Doxorubicin, and β-	1
	Ì	Glucuronidase-Activated Prodrug (HMR 1826)", Anticancer Research,	ĺ
		(2000),2289-2296	
		WOJCIK, "Inhibition of the proteasome as a therapeutic approach", Drug	1
		<u>Discovery Today, 4 (4), (April 1999), 188-189</u>	
		WOJCIK, CEZARY, et al., "Lovastatin and simvastatin are modulators of the	
	i	proteasome", International Journal of Biochemistry & Cell Biology, (32),	
		(2000),957-965	
		WORKING, PETER, et al., "Pharmacological-Toxicological Expert Report	
		CAELYX™ (Stealth Liposomal Doxorubicin HCI)", Human & Experimental	
		<u>Toxicology</u> , (1996),752-785	_
		XIAO, W., et al., "Adeno-Associated Virus as a Vector for Liver-Directed Gene	
		Threapy", Journal of Virology, 72 (12), (1998),pp. 10222-10226	
		YAN, Z., et al., "[20] Recombinant AAV-Mediated Gene Delivery Using Dual	
		Vector Heterodimerizatiion", In: Methods in Enzmology, Vol. 346: Gene Therapy	
		Methods, Phillips, M. I., Editor, Academic Press, San Diego, CA,(2002),334-357	<u> </u>
		YAN, ZIYING, et al., "A Common Theme for Ubiquitination-Dependent	
		Transduction of rAAV Type 2 and 5", American Society of Gene Therapy,	
		Abstracts of Scientific Presentations, (Abstract No. 569),(June 5, 2002), 1 pg.	
•		YAN, Z., et al., "Distinct Classes of Proteasome-Modulating Agents	
	1	Cooperatively Augment Recombinant Adeno-Associated Virus Type 2 and	
		Type 5-Mediated Transduction From the Apical Surfaces of Human Airway	1
		Epithelia", Journal of Virology, 78(6), (March, 2004),2863-2874	

Kevin K. Hill

Approved for use through 10/31/2002, CMB 651-0031

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 16 of 16	Attorney Docket No: 8	375.085US1	

	OTHE	R DOCUMENTS - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		YAN, Z, et al., "Trans-splicing vectors expand the utility of adeno-associated virus for gene therapy", Proc. Natl. Acad. Sci. USA, 97, (June 6, 2000),6716-6721	
		YANG, J., et al., "Concatamerization of Adeno-Associated Virus Circular Genomes Cocurs Through Intermolecular Recombination", <u>Journal of Virology</u> , 73 (11), (Nov. 1999),9468-9477	
		ZABNER, J, et al., "Adenovirus-mediated gene transfer to ciliated airway epithelia requires prolonged incubation time", <u>Journal of Virology</u> , 70(10), (October, 1996),6994-7003	
		ZABNER, J, et al., "Adenovirus-mediated generation of cAMP-stimulated Cl- transport in cystic fibrosis airway epithelia in vitro: effect of promoter and administration method", Gene Therapy, 3, (1996),pp. 458-465	
		ZENTNER, M. D., "The Amiloride-Sensitive Epithelial Sodium Channel a- Subunit is Transcriptionally Down-Regulated in Rat Parotid Cells by the Extracellular Signal-Regulated Protein Kinase Pathway", <u>The Journal of</u> Biological Chemistry, 273(46), (1998),30770-30776	
		ZHOU, LIQIAO, et al., "Improvement of Transduction Efficiency from Split AAV Vectors", American Society of Gene Therapy, (Abstract Only), Abstracts of Scientific Presentations, (June 5, 2002), 1 pg.	

PTC/SBR084 (10-01)
Approved for use through 1031/2002, OMB 651-0001
US Please & Tradement Office, U.S. DEPARTMENT OF COMMERCE
r the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains e valid OMB control number,
omplete if Known SDOSLITUTE FOR FORM 1449APTO INFORMATION DISCLOSURE Complete if Known **Application Number** 10/815,557 STATEMENT BY APPLICANT Use as man Psipels as necessary) March 31, 2004 **Filing Date First Named Inventor** Engelhardt, John 1653 **Group Art Unit** APR 2 7 2006 **Examiner Name** Unknown Attorney Docket No: 875.085US1

		US PAT	ENT DOCUMENTS	
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2001/0034349A1	10/25/2001	Boucher, Jr., R. C.	02/20/2001
- · - · -	US-2001/0041682A1	11/15/2001	Stutts, III, M. J., et al.	05/07/2001
·	US-2002/0099023A1	07/25/2002	Boucher, Jr., R. C.	03/01/2002
	US-2002/0115619A1	08/22/2002	Rubenstein, R. C., et al.	10/04/2001
	US-2002/0128203A1	09/12/2002	Schild, L.	09/19/2001
	US-2002/0132770A1	09/19/2002	Caplan, M. T., et al.	10/12/2001
	US-2002/0156057A1	10/24/2002	Bubien, J. K.	04/19/2002
	US-2002/0158255A1	10/31/2002	Boucher, Jr., R. C.	04/12/2002
	US-2002/0165239A1	11/07/2002	Boucher, Jr., R. C.	04/12/2002
	US-2003/0087818A1	05/08/2003	Jiang, Y., et al.	02/01/2002
	US-4,501,729	02/26/1985	Boucher, R. C., et al.	12/13/1982
	US-5,292,498	03/08/1994	Boucher, Jr., R. C.	06/19/1991
	US-5,512,269	04/30/1996	Molina y Vedia, L. M., et al.	06/09/1993
	US-5,628,984	05/13/1997	Boucher, Jr., R. C.	07/31/1995
-	US-5,635,160	06/03/1997	Stutts, III, M. J., et al.	06/07/1995
	US-5,651,957	07/29/1997	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,656,256	08/12/1997	Boucher, R. C., et al.	12/14/1994
	US-5,683,675	11/04/1997	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,716,931	02/10/1998	Molina y Vedia, L. M., et al.	05/02/1995
	US-5,725,842	03/10/1998	Boucher, Jr., R. C., et al.	01/05/1996
	US-5,849,706	12/15/1998	Molina y Vedia, L. M., et al.	01/28/1998
	US-5,855,918	01/05/1999	Mrsny, R. J., et al.	09/12/1996
	US-5,876,700	03/02/1999	Boucher, Jr., R. C., et al.	01/31/1997
	US-5,902,567	05/11/1999	Boucher, Jr., R. C.	12/30/1996
	US-5,935,555	08/10/1999	Stutts, III, M. J., et al.	05/08/1977
	US-6,022,527	02/08/2000	Boucher, Jr., R. C., et al.	07/13/1999
	US-6,033,688	03/07/2000	Mrsny, R. J., et al.	09/02/1997
-	US-6,133,247	10/17/2000	Boucher, Jr., R. C.	07/24/1996
	US-6,143,279	11/07/2000	Boucher, Jr., R. C., et al.	08/28/1998
	US-6,214,536	04/10/2001	Boucher, Jr., R. C.	11/04/1999
	US-6,235,266	05/22/2001	Stutts, III, M. J., et al.	04/30/1999
	US-6,264,975	07/24/2001	Boucher, Jr., Richard C.	10/20/1999
	US-6,323,187	11/27/2001	Yerxa, B. R., et al.	05/21/1999
	US-6,416,759	07/09/2002	Firestone, G. L., et al.	09/30/1999
	US-6,420,347	07/16/2002	Jacobus, K. M., et al.	03/27/1997
	US-6,451,288	09/17/2002	Boucher, Jr., R. C., et al.	08/24/2000
	US-6,475,509	11/05/2002	Boucher, Jr., R. C.	07/19/2000
	US-6,607,741	08/19/2003	Boucher, Jr., R. C.	04/12/2002
	US-6,613,345	09/02/2003	Boucher, Jr., R. C.	04/12/2002

**EXAMINER** 

Kevin K. Hill

PTO/SB/084/10-01)
Approved for use through 10/31/2002, OMB 651-0031
US Paiert & Trademark Office: U.S. DEPARTMENT OF CONMERCE

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 2 of 3	Attorney Docket No: 8	375.085US1	

	FOI	REIGN PATENT I	DOCUMENTS	
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T²
	WO-02/24172A1	03/28/2002	Vanderbist, F., et al.	
	WO-02/24177A2	03/28/2002	Schild, L., et al.	
	WO-03/057847A2	07/17/2003	Shuster, S. J., et al.	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	4
Examiner Initials*	Cite No 1	Include name of the author (In CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AUERBACH, S. D., et al., "Human Amiloride-Sensitive Epithelial Na* Channel y	1
		Subunit Promoter: Functional Analysis and Identification of a Polypurine-	
		Polypyrimidine Tract With the Potential for Triplex DNA Formation", The	İ
		Biochemical Journal, 347, (2000), 105-114	
		BAINES, D. L., et al., "Effect of LPS-Induced NF-kB Activity on the	1
		Transcriptional Response of a 5' Flanking Region of the aENaC Gene",	
		Experimental Biology 2003 - Translating the Genome, (Abstract No. 5860)	
		(http://www.biosis-select.org/faseb/data/FASEB005860.html,(2003), 1 pg.	<u> </u>
		BEUTLER, K. T., et al., "Long-Term Regulation of ENaC Expression in Kidney	
		by Angiotensin II", <u>Hypertension</u> , 41, (2003),1143-1150	
	1	BOOTH, R. E., et al., "Targeted Degradation of ENaC in Response to PKC	Т
		Activation of the ERK1/2 Cascade", American Journal of Physiology - Renal	1
		Physiology, 284, (2003), F938-F947	1
		ECELBARGER, C. A., et al., "Regulation of the Abundance of Renal Sodium	1
		Transporters and Channels by Vasopressin", Experimental Neurology, 171,	1
,		(2001), 227-234	
		FALLIN, R. A., et al., "PMA-Induced Inhibition of Amiloride-Sensitive Sodium	Τ
		Absorption is Partially Mediated by ERK1/2 Activation", The FASEB Journal,	
		17(5) (Abstracts Part II), (Abstract No. 585-19), (2003), A915-A916	
		GADALLAH, M. F., et al., "Epithelial Sodium Channel-Dependent Hyptertension:	Τ
		An Emerging Syndrome", Journal of the American Society of Nephrology, 10	1
		(Abstracts Issue), (Abstract No. A1842), (1999), page 365A	
		GADALLAH, M. F., et al., "Preservation of Renal Function in Patients With	1
		Hypertension and Chronic Renal Impairment; Revisited", Journal of the	ı
		American Society of Nephrology, 10 (Abstracts Issue), (Abstract No. A1841),	
		(1999), page 365A	
		GORMLEY, K., et al., "Regulation of the Epithelial Sodium Channel by	1
	1	Accessory Proteins", The Biochemical Journal, 371, (2003), 1-14	1
	-	HUMMLER, E., et al., "Genetic Disorders of Membrane Transport - V. The	$\top$
		Epithelial Sodium Channel and its Implication in Human Diseases", American	.
		Journal of Physiology - Gastrointestinal and Liver Physiology, 276, (1999),	
		G567-G571	

Kevin K. Hill

**DATE CONSIDERED** 

May 8, 2007

PTO/SB/08A(10-01)
Approved for use through 10/31/2002 OMB 651-0031
S Petrel & Tredwinkh Office: U.S. DEPARTMENT OF COMMERCE of information unless the commence of information unless the commence of the comme

Substitute for form 1449APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Uso as many sheets as nocessary)	Under the Peparwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid DMB control number Complete if Known		
	Application Number	10/815,557	
	Filing Date	March 31, 2004	
	First Named Inventor	Engelhardt, John	
	Group Art Unit	1653	
	Examiner Name	Unknown	
Sheet 3 of 3	Attorney Docket No: 875.085US1		

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1,3
		JORGENSEN, M. J., et al., "Expression of Completely y-Carboxylated	
		Recombinant Human Prothrombin", The Journal of Biological Chemistry,	
		<u>262(14)</u> , (1987), 6729-6734	
	1	KAMYNINA, E., et al., "Concerted Action of ENaC, Nedd4-2, and Sgk1 in	1
		Transepithelial Na <sup>+</sup> Transport", American Journal of Physiology - Renal	
·		Physiology, 283, (2002), F377-F387	
		MATALON, S., et al., "Lung Edema Clearance: 20 Years of Progress - Invited	1
		Review: Biophysical Properties of Sodium Channels in Lung Alveolar Epithelial	
		Cells", Journal of Applied Physiology, 93, (2002), 1852-1859	
		MIRSHAHI, M., et al., "Paradoxical Effects of Mineralocorticoids on the Ion	
	İ	Gated Sodium Channel in Embryologically Diverse Cells", Biochemical and	
		Biophysical Research Communications, 270, (2000), 811-815	ļ
		NAKAYAMA, M., et al., "Hypomethylation Status of CpG Sites at the Promoter	
		Region and Overexpression of the Human MDR1 Gene in Acute Myeloid	
		Leukemias", <u>Blood, 92(11),</u> (1998), 4296-4307	
		ROTIN, D., "Regulation of the Epithelial Sodium Channel (ENaC) by Accessory	
		Proteins", Current Opinion in Nephrology and Hypertension, 9, (2000),529-534	
		ROTIN, D., et al., "Trafficking and Cell Surface Stability of ENaC", American	
		Journal of Physiology - Renal Physiology, 281, (2001), F391-F399	
		SNYDER, P. M., et al., "Serum and Glucocorticoid-Regulated Kinase Modulates	
		Nedd4-2-Mediated Inhibition of the Epithelial Na* Channel", The Journal of	
		Biological Chemistry, 277(1), (2002), 5-8	
		THOMAS, C. P., et al., "Genomic Organization of the 5' End of Human &-ENaC	
		and Preliminary Characterization of its Promoter", American Journal of	
		Physiology - Renal Physiology 282, (2002), F898-F909	